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THE USE OF SOCIETAL CRITERIA IN PRIORITY SETTING FOR HEALTH TECHNOLOGY ASSESSMENT IN THE NETHERLANDS

Initial Experiences and Future Challenges

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Abstract

Priority setting for the evaluation of health technologies in the Netherlands is exclusively based on the scientific merits of individual research proposals. This process has not resulted in satisfactory allocation of resources. Therefore, societal criteria for setting priorities for health technology assessment have been proposed as an adjunct to scientific criteria. These societal criteria include the burden of disease, uncertainty about the (cost-)effectiveness of the intervention at issue, the potential benefits of the research project, and its potential impact on health care. To realize the full potential of this model for priority setting, a number of methodological issues need to be addressed. Joint efforts of researchers and policy makers in this field are necessary for future progress.

Health technology assessment (HTA) in the Netherlands was introduced around 1982 when the Dutch Health Insurance Council was confronted with patients demanding reimbursement of the costs of heart and liver transplantations that had been performed abroad. This debate stimulated a new policy, outlined in the paper on limits to the expansion of the benefit package (23). The policy held stated that, as a prerequisite for coverage in the benefit package, the efficacy and cost-effectiveness of all major new health technologies ought to be assessed.

In 1988 the Dutch government recognized the need for a systematic approach to HTA, which resulted in the establishment of the Investigative Medicine Programme of the Dutch Health Insurance Council. This program, which allocates a

budget of US \$21 million on an annual basis, is still the most important program for HTA in the Netherlands. Predominantly universities and university hospitals submit research proposals to this program. Only about 20% of research proposals submitted to the Investigative Medicine Programme are granted as a result of rigorous scientific assessment. The Dutch Health Insurance Council is not always satisfied with the outcome of the selection process, as some of the selected research proposals are not considered a high priority in Dutch health care (2;4;5;7;9;10). Therefore, the Dutch Health Insurance Council decided to develop a model for priority setting for HTA on the basis of societal criteria, which are to be used as an adjunct to scientific criteria.

However, the methodology of determining the societal relevance of research proposals is not yet established (10;28;32;43). This article reviews the initial experiences with this model of priority setting and identifies some of its future challenges. First, two procedures for submitting research proposals as part of the Investigative Medicine Programme are described. Second, four dimensions of societal relevance of HTA are distinguished, followed by an account of the possibilities and problems of setting priorities under this program. To use societal criteria for priority setting in an explicit, systematic, and transparent way, a number of methodological issues need to be addressed.

Procedures for submitting research proposals

In the Netherlands, submission of research proposals for HTA is organized by the Health Insurance Council in two different procedures.

The first procedure simply consists of a call for research proposals, which have to conform to general criteria defining the borders and goal of the Investigative Medicine Programme. In the next step the scientific quality of the submitted proposals is assessed. Then, scientific criteria and, occasionally, societal criteria are applied in a priority-setting process. This is the so-called "bottom-up" procedure of the program. The scientific review of this procedure is very rigorous, and not enough proposals meet scientific criteria to spend the entire annual budget. Therefore, no priorities needed to be set beyond scientific relevance. Until 1996 about 100 research proposals have been granted within the "bottom-up" procedure, of which 26 have been completed (19). Examples are evaluation of autologous bone marrow transplantation for patients with malignant lymphoma and evaluation of excimer laser coronary angioplasty (ELCA) versus percutaneous transluminal coronary angioplasty (PTCA) in patients with long coronary artery stenosis.

In the second procedure, which started in 1993, selected groups of researchers are invited to submit a full research proposal focusing on a specific subject. The scientific merit of the research proposals is assessed. Only those proposals are eligible for assessment that address the selected subject. This is the so-called "top-down" approach of the program. Until mid 1996 two research proposals had been granted: validation treatment of patients with dementia and treatment of urinary incontinence (20;21).

As HTA consumes a fair amount of resources, it is surprising how little is known about the effectiveness of the methods for allocation of research grants as described above. It is unclear which method for determining societally relevant research proposals is the best. Moreover, little is known about the efficiency of the selection procedures.

Societal relevance

Several attempts have been made to address the issue of determining the societal relevance of research proposals for HTA, for example in the United States and in the United Kingdom (12;13;27;33;34). Several criteria for setting priorities can be found in the international literature. These criteria can be categorized in four dimensions (7).

The first dimension is the burden of disease. Burden of disease can be described in terms of prevalence and incidence figures, the mean burden per individual, and the societal costs of the disease. This dimension can be characterized by a number of indicators, of which some are available in literature, although typically information is scarce.

The second dimension is uncertainty about the effectiveness and efficiency of the intervention or health service at issue. This uncertainty can be inferred from variation in use among professionals, regions and/or countries, or lack of agreement among physicians about the indications for use. However, it is possible that existing knowledge is available but not being consistently applied in clinical practice. Moreover, absence of clinical practice variation does not guarantee effective and efficient care. In some cases, where multiple randomized clinical trials (RCTs) are available, meta-analysis can be quite helpful. Information on ongoing research, which has the potential to reduce uncertainty, is also necessary when assessing the societal relevance of future research.

The third dimension is the potential benefits of the assessment. Potential benefits can be an improvement in health status and/or savings in resources when, for example, a new health technology is introduced or when an ineffective health technology is abandoned. An estimate of the potential benefits should preferably be based on empirical research, in which all relevant alternatives should be taken into account.

The fourth dimension is the potential impact of the proposed research project. This implies a necessarily subjective assessment of its potential to change clinical practice, the organization, or the financing of care. The anticipated impact of the assessment can be seen as a necessary criterion of societal relevance if we consider health care research as a means to improve public health.

Setting priorities for health technology assessment

In late 1995 the Dutch Minister of Health presented a policy document about HTA and efficiency of care to the Dutch Parliament. The policy document states that to increase the practical application and impact of HTA research, the various activities need to be better coordinated. Furthermore, priorities are not sufficiently well identified (30). The Dutch Council for Health Research is charged with these tasks. In early 1997 the Council initiated research for identifying priorities for HTA (29). The results of the priority-setting process for HTA need to be clearly presented before effective policy mechanisms can be implemented. In general, criteria for setting priorities need to be derived from the goals of the funder. The level of setting priorities also needs to be clear; priorities can be set regarding research programs, health problems, or specific research questions or research proposals. Setting priorities for HTA allows the resources available for research to be focused on assessments that will contribute most to the goals of a particular program. Although every program will have its own procedure of setting priorities, it will be faced with several common problems.

One problem is systematic identification of topics for priority setting. In order to identify priorities for HTA, it is necessary to select from a pool of potential topics. This implies the monitoring of issues that are or should be of concern to the funders, identifying possible HTAs on these issues that could assist decision making. Ten years ago the Steering Committee for Future Health Care Scenarios was active in the field of monitoring health technologies. On a regular basis the Dutch Health Council identifies relevant new health technologies for assessment. Although this monitoring system is thought to be working quite well, more attention should be paid to extramural technologies, nursing technologies and, new procedures (30).

After identification of a potential topic, a well-defined research question needs to be formulated. Often a research question focuses on a combination of an intervention and its putative indication (9). Rapid technological developments may complicate assessing new health technologies. Criteria for judging the benefit likely to result from an assessment addressing the research question need to be well described (32). The quality of this description depends on the availability of relevant information.

The relative weighting of the societal criteria is also a problem in the priority-setting process. Several methods for weighting have been proposed that are mostly mathematically oriented (12;13;27;35). However, there is no consensus on the best method (1;32;42). This also pertains to the way in which scientific quality is combined with a judgment about the societal relevance of a research proposal. A solution for this latter problem is restricting the priority-setting process to those research proposals that are already judged to be scientifically sound.

The effort and resources needed for executing the research project at issue also influences priority setting. A research proposal that is relatively cheap and the societal relevance of which is judged to be modest can still be given a high priority. Since HTA is also aimed at determining the cost-effectiveness of health care technologies, it is important to ensure that the process of assessment—including the process of setting priorities—is cost-effective as well (42). Bonsel and Rutten (6) made a first attempt to document this, relating the resources devoted to assessment to the costs of health care in the case of heart and liver transplantation and in vitro fertilization (IVF). The authors state that an assessment can be performed in a more efficient way if researchers have experience with performing assessment studies, and when collection of primary data is not necessary. In complementary cases, where primary data collection is judged to be necessary, the costs of data collection should be related to the expenditures of the technology under study (6).

These problems did not diminish the increasing attention to priority setting on the basis of societal criteria. Examples of priority setting of general topics are published in the report on chronic diseases by the Council for Health Research (36) and in the Strategy Report 1996–2001 by the Board for Medical Science of the Netherlands Organization for Scientific Research (NWO-MW) (31;41). Both contain a description of topics based on indicators of the magnitude of the problem, on the one hand, and available empirical evidence on the other. Experts were consulted, but the way in which consulting was structured is not well described. In both publications several topics are identified that should be given priority, but a relative ranking of these topics is lacking. An attempt to rank topics was published in a report on the cost-effectiveness analysis of existing provisions of the Dutch Health Insurance Council (22). Two brainstorming sessions were held with medical

advisers of insurance companies and medical insurance boards regarding the priority-setting process. The Council invited a large number of experts to judge priorities for cost-effectiveness analysis of existing provisions. Experts included 11 medical specialists, 10 general practitioners, 2 dentists, 1 nurse, and 3 hospital directors. Finally, a list of 126 potential topics was generated, which were then ranked on the basis of their societal relevance. The top 10 of this list include:

1. Ultrasound treatment for problems of the locomotor system;
2. Treatment and care of nonhospitalized acute psychiatric patients;
3. Specialist care for chronic patients
4. Diagnosis of suspected herniated nucleus pulposus;
5. Diagnostic arthroscopy of the knee compared to diagnostic magnetic resonance imaging (MRI);
6. Expanded laboratory testing by general practitioners;
7. Intensive care;
8. Palliative treatment in oncology;
9. Treatment of chronic benign pain; and
10. Electrical treatments in physiotherapy (3).

This was the first time that such a list became available in the Netherlands and the first attempt to rationalize priority setting for HTA. This approach was debated intensely (2;4;5;9;10;15;19;24;28;32;42;43). Although imperfect, this list was judged to be useful for follow-up activity by both the Dutch Health Insurance Council and the Health Council, who jointly work on the further development of the list (30). In addition, this list is used as an input for the top-down approach of the Dutch Health Insurance Council, which will be further described as a case study below.

The 'top-down' approach of the Dutch Fund for Investigative Medicine

The primary goal of the Dutch Fund for Investigative Medicine is to support research that produces information on the effectiveness and efficiency of health technology. The program also supports assessments related to the societal, ethical, and legal aspects of the use of health technology. Both new and existing technologies can be eligible for the program. The information should be useful for decision making by the government and others, including providers of health care. In particular, the information should be useful to support decision making on including programs in the social benefit package. Although, initially, a bottom-up procedure was used to select projects, it was recognized that this approach resulted in underrepresentation of, among other technologies, diagnostic technologies, long-term care, and mental health care interventions. This led the Investigative Medicine Committee and its secretariat to consider alternative methods of selecting projects. After some discussion, the idea of a top-down approach evolved. Based on existing priority lists and internal discussions, three priority topics were selected: treatment of urinary incontinence, treatment of psychogeriatric problems (especially dementia), and assessment of diagnostic problems using MRI. Researchers could express their interest in evaluating one of these topics by means of a short description of a research proposal. The Committee intended to select a limited number of research groups per topic who would receive payment for producing full-length research proposals. This method of recruiting proposals was successful in terms of the extremely high number of descriptions of proposals that were submitted, but at the

same time it became apparent that the research question had not been specified sufficiently. Instead of reflecting the interests of the Investigative Medicine Committee, the priority topics had been interpreted in a way that primarily seemed to fit the interests of the researchers. This situation complicated the selection procedure considerably, both in the initial selection of preliminary proposals and the final selection of full proposals. For these reasons it was decided to formulate highly detailed research questions in preparation of the second round of the top-down procedure. Just as the first round, the second round uses societal criteria in the selection process. In particular, the relevance of each proposal for policy making regarding the social benefit package should be obvious. Furthermore, the demand for scientifically sound proposals will be fully maintained. All future proposals will have to include a full economic evaluation: both costs and consequences of at least two alternatives will have to be included in the study, usually organized as a RCT.

The priority-setting process should be as transparent and as explicit as possible. In order to achieve these goals, the four dimensions of societal relevance will be applied: burden of disease, uncertainty, the potential benefits of assessment, and the impact of assessment. The questions related to the first three dimensions could be answered by means of systematic literature reviews and from other sources (8). The questions related to the fourth dimension, and to some extent with the third dimension, may be answered primarily by systematic expert consultation. Much attention will be paid as well to the phenomenon of unexplained clinical variation, which pertains to clinical practice variation between physicians, regions, or countries that cannot be attributed to differences in the prevalence of disease and/or differences in morbidity. In addition, high priority will be given to preventive health technologies and new diagnostic technologies or therapeutic technologies that are on the brink of rapid, uncontrolled diffusion in the health care system without evidence of safety, effectiveness, and cost-effectiveness. Of course, this is of particular importance in the case of expensive interventions.

The starting point for this priority-setting exercise is the report on cost-effectiveness analysis of existing provisions, the so-called "126 list" outlined above (22). The first 50 topics of this list are selected for actual assessment. Recently the Health Council assessed the "126 list," which resulted in a selection of 17 topics for a synthesis of available scientific literature (18). New topics for inclusion in the resulting "50 list" have been suggested by the Ministry of Health, university hospitals, insurance companies, and medical societies. A procedure that facilitates suggestions for inclusion of new topics has yet to be devised. All suggestions will be screened using the priority-setting dimensions discussed earlier. Annually, three to five topics will be selected for the top-down program using the "50 list" as the source. To support the selection process, systematic literature reviews will be commissioned in specific cases. The proposal will be granted when it is of sufficient methodological quality and when it demonstrates the potential to provide an adequate answer to the specified research question. Of course, it is planned to periodically revise the "50 list." New topics deserving high priority will be added to the list, while topics that have been translated into research proposals will be withdrawn from the list. For example, in 1997 the Health Council added oral hygiene and the treatment of dyslexia (29). Similarly, topics the priority of which is reduced due to, for example, recent technological developments or publications of relevant studies performed elsewhere, may be withdrawn from the list.

DISCUSSION

Although priority setting of HTA has been tried, the methods used are typically not very straightforward, and explicit criteria are seldom used. One reason for this situation is that methods for setting priorities on the basis of societal criteria are not well developed. A second reason is that crucial elements in priority setting are still not based on sound (scientific) evidence. As a result, the priority-setting process in the Investigative Medicine Programme faces a number of challenges. The most important challenges include the need to balance the financing of the top-down and the bottom-up procedure, the identification of topics for HTA, the translation of policy-oriented questions to well-designed research questions, and the improvement of the effectiveness of the priority-setting process (32).

Balance the Financing of the Top-down and the Bottom-up Procedure

The topic of balance was discussed in Parliament in May 1996, when a member of Parliament introduced a motion urging the government to press the Health Insurance Council to put more emphasis on the "126 list" by reserving less money for the bottom-up part of the procedure. In addition, the Health Insurance Council was asked to consider the restructuring of its Investigative Medicine Committee to a committee devoted to reducing inefficiency in public health insurance (21). This motion, which passed the Parliament, was fully supported by the Dutch Minister of Health. Subsequently, the Investigative Medicine Committee decided to allocate 6 million Dutch guilders (US \$3.5 million) for the top-down procedure in 1998, and 30 million Dutch guilders (US \$17 million) for the bottom-up procedure. This represents a 100% increase of the annual budget for the top-down procedure compared to former years.

Topics for HTA

In the past, the Investigative Medicine Committee rarely accepted proposals for the evaluation of pharmaceuticals (20;21). This policy will become more liberal now that the Dutch Minister of Health has allocated an additional US \$11.5 million for economic evaluation of pharmaceuticals that are clinically significantly different from existing pharmaceuticals, and in cases where the advent of new drugs constitute treatment-indication combinations that did not exist before. This program will probably be implemented in 1997.

Translation of a Policy-oriented Question to a Well-defined Research Question

Two prerequisites can be identified for a successful "translation" of a policy-oriented question to a well-defined research question: researchers need to be made aware of health policy issues, and policy makers need to be made aware of assessment procedures. This interaction could create the climate to design the assessment in such a way that the results provide enough information for answering the policy-oriented question. Another way to facilitate a successful translation is to include a section on policy-oriented issues in the application form. This has become common practice in the Investigative Medicine Programme.

Validity of the Priority-Setting Process

A number of national and international activities have been initiated to contribute to improving the validity of the priority-setting process. These can be divided according to each of the four dimensions of societal relevance.

Regarding the first dimension, burden of disease, the report on investing in health, by the World Bank, plays a role. This report stimulated discussion about the concept of measuring the burden of disease, which is still controversial (40). On the national level the National Institute for Health and Environmental Hygiene published a major report on exploring the future of public health in 1993 (38). The report on cost of diseases in the Netherlands by the Department of Public Health of the Erasmus University (26) is also important in this particular context.

The activities of the Cochrane Collaboration focus on the second dimension, aimed at the reduction of uncertainty. The Cochrane Collaboration has developed a method for performing systematic reviews of evidence, especially evidence from RCTs which are collected in a database (11;44). The first Cochrane Centre was set up in the United Kingdom in 1992, and since then the Collaboration has grown enormously. In the Netherlands a Cochrane Centre was established in 1994, funded by the Dutch Ministry of Health (25). The Cochrane Library can be used as an input for developing guidelines and standards for health care professionals (30). The Collaboration is also stimulating adequate registries of ongoing research projects. This is already a tradition in social sciences but not (yet) in health sciences and in medicine.

International activities with regard to the third dimension, the potential benefit of the assessment, include the European projects HARMET and EUR-ASSESS. HARMET is a project the basic aim of which is to develop consensus on the methodology for economic evaluation of health technologies in the European Union. Five areas were identified for operational purposes: a) definition of concepts and terminology (e.g., health effects, benefits); b) general methodological issues (e.g., time horizon, discount rate); c) cost measurement (e.g., consensus about accounting rules); d) outcome measurement (e.g., consensus about health effects); and e) presentation of results—applicability of economic analysis to decision making (37). EUR-ASSESS is a program for communication and coordination of HTA. Thirty-three organizations in 15 countries participated in EUR-ASSESS, divided into four subgroups: priority setting (to improve priority setting in HTA); methodology (to improve methods of assessment); dissemination (to improve methods of dissemination of HTA as well as evaluation of results); and coverage (to promote the use of technology assessment in health insurance coverage decisions). In the meantime a follow-up activity has been initiated, aimed at strengthening the development of HTA in the European Community (HTA-Europe). National activities include the Working Group Health Status Research, which was initiated in 1992 and aims at improving standards for measuring health status (14), and the report of the Steering Committee for Future Health Care Scenarios on guidelines for cost calculations in health services research (39).

The policy document about HTA and efficiency of care of the Dutch Ministry of Health can be mentioned with regard to the fourth dimension, impact of assessment (30). In the document much attention was given to the implementation of assessment results. The government and several national organizations are encouraging professionals to implement assessment results by funding activities.

Priority setting of HTA on the basis of societal criteria creates relevant knowledge for policy making. This does not necessarily imply rational policy: scientific knowledge is just one of the many determinants of policy on the level of the individual as well as on the societal level. However, use of societal criteria in setting priorities of health technology assessment is necessary in making rational choices

and improves evidence-based medicine and evidence-based health policy making (16;17;45).

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